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On behalf of: Patent Owner Illumina Cambridge Ltd.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTELLIGENT BIO-SYSTEMS, INC.

Petitioner,

v.

ILLUMINA CAMBRIDGE LTD.

Patent Owner.

Case IPR2013-00517

U.S. Patent 7,566,537

ILLUMINA'S OPPOSITION TO IBS MOTION TO EXCLUDE EVIDENCE

Columbia Exhibit 2042

Illumina, Inc. v. The Trustees of Columbia

University in the City of New York

IPR2018-00322

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Patent Owner Illumina Cambridge Ltd. (“Illumina”) opposes IBS’ Motion to Exclude Evidence (Paper 61). *See* Paper 17 & 37 C.F.R. § 42.23.

Ex. 2003 Is Admissible

Ex. 2003 is admissible under FRE 803(6) & 902(11). Illumina provided a declaration from a qualified witness, Ms. Espejo, certifying that she understands the record keeping systems at Solexa Ltd. (now called Illumina) and further certifying that Solexa’s company policy required scientists to regularly record the results of daily experiments in laboratory notebooks that were appropriately signed, witnessed, and archived. Ex. 2127, ¶2. Ex. 2003 was made, at or near the time of, the occurrence by a person with knowledge acting within the regular conduct of business. Ex. 2127, ¶3. Ms. Espejo is not required to have personal knowledge of the actual creation of Ex. 2003 or to have assembled the exhibit. *Conoco Inc. v. Dept. of Energy*, 99 F.3d 387, 391 (Fed. Cir. 1996). Ms. Espejo must only understand the record keeping systems. *Id.* She so certified under oath. Ex. 2027. Furthermore, Rule 803(6) does not require Ex. 2003 to be prepared by the business entity proffering the document. *Air Land Forwarders, Inc. v. United States*, 172 F.3d 1338, 1342–44 (Fed. Cir. 1999). Ms. Espejo’s declaration states that Illumina Inc. incorporated Ex. 2003 into the business records of Illumina Inc. and that Illumina Inc. relies on the accuracy of these pages. Ex. 2127, ¶5. Thus, Ex. 2003 is admissible under FRE 803(6) & 902(11). Unlike *Wojciak v. Nishiyama*,

Int. 104,539 (McK), 2001 WL 1675462, *6–7 (BPAI June 4, 2001), Ex. 2127 provides un rebutted, credible evidence that all relevant information was required to be entered into notebooks by Solexa scientists. IBS declined to depose Ms. Espejo, or seek to depose the author of Ex. 2003. Furthermore, Dr. Romesberg explained Ex. 2003 in his declaration and was deposed by IBS. Ex. 2011, ¶¶66-81; Ex. 1025.

IBS also moves to exclude Ex. 2003 under FRE 106. But, FRE 106 is not an exclusionary rule. Rather, FRE 106 permits the introduction of other documents in the interest of fairness, and places the burden on IBS to introduce those documents. Despite access to a vast number of Illumina documents produced in the related litigation, including dozens of laboratory notebooks, IBS only introduced a single four–page experiment (Ex. 1042) for consideration with Ex. 2003. Finally, Ex. 2003 is relevant because it provides data probative of the unexpected and superior properties of the claimed methods over the closest art.

Exs. 2006–2009 Are Admissible

Exs. 2006–2009 are relevant because they include admissions that undermine and contradict the entire basis for IBS’ obviousness position. IBS’ admission in Ex. 2006 is particularly relevant. There, “Applicants [IBS] respectfully submit that there is no basis for the combination” of methods for labeling nucleic acid molecules (Ex. 2030, “Dower,” 18:64-19:10, Fig. 9) with the 3’-O-azidomethyl ether of Zavgorodny (2000). Ex. 2006 at 9. Illumina agrees –

there is no basis for combining a method for labeling nucleic acid molecules with Zavgorodny's 3'-O-azidomethyl ether. Indeed, the record shows that the combination would have been expected to be incompatible. Paper 32 at 3–4.

IBS asks the Board to ignore its admission regarding the non-combinability of Zavgorodny and labeling methods (Dower) because IBS made *additional* arguments in its response to the office action. That is not a sufficient reason to ignore the highly relevant admissions in Ex. 2006, let alone a reason to exclude it.

Exs. 2007–2009 are published patent applications from IBS that claim azido and azidomethyl protecting groups and do not claim allyl protecting groups. Exs. 2007–2009 show that IBS itself has viewed azido and azidomethyl groups as valuable and superior over allyl groups. Additionally, these exhibits are relevant because they further support Illumina's position that IBS abandoned its allyl-based method in favor of Illumina's azidomethyl-based method. *See, e.g.*, Ex. 2008 at 100 & Paper 32 at 57-58; *see also* Ex. 2089, ¶¶45-52 & 65-74.

Exs. 2027, 2075, 2076, And 2050 Are Admissible

IBS is required to explain each of its objections, but failed to do so. 77 Fed. Reg. 48765, 48767 (Aug. 14, 2012). For example, IBS objects to Exs. 2075 & 2076 as “irrelevant.” Paper 61 at 5, n.2. Such allegations are insufficiently explained, making it difficult to respond, and IBS's motion should be denied for at least this reason.

Furthermore, Ex. 2050 is not hearsay because it is offered as evidence of what people in the art were communicating at that time about Illumina's technology. *See* FRE 803(3). The statements in Ex. 2050 are relevant to show that others viewed Illumina's results as unexpected and as fulfilling a long-felt need.

The statements in Exs. 2027, 2075 & 2076 are non-hearsay under FRE 803(18) because Dr. Romesberg established Exs. 2027, 2075 & 2076 as reliable authorities and relied on them to support his opinion that Illumina's results were unexpected and surprising. Ex. 2011, ¶61. The statements in Ex. 2050 are admissible under FRE 807 because they were published by a highly-respected scientific journal and are consistent with Dr. Romesberg's declaration.

IBS' relevancy objections go to the weight of the evidence, not admissibility. IBS does not dispute that Bentley's "approach" included the use of "four reversible terminators, 3'-O-azidomethyl 2'-deoxynucleoside triphosphates (A, C, G and T), each labelled with a different removable fluorophore." Ex. 2027 at 53. IBS' expert confirmed that Illumina's novel protecting group was an important factor in Bentley's sequencing system. Ex. 2154, 203:10–209:3, 247:13–205:1

Contrary to IBS' accusation, Illumina did not mischaracterize Ex. 2050. It is undisputed that Illumina's system uses nucleotides with a cleavable azidomethyl 3' protecting group and IBS' expert confirmed that those in the art knew that

Illumina's commercial products employed azidomethyl protecting groups. Ex. 2154, 110:23–111:6. Accordingly, because Illumina's systems discussed by Exs. 2027 & 2050 employed the recited azido-containing protecting group, the successful results are probative of non-obviousness. The fact that such results were published in *Nature* further supports their recognized significance. Exs. 2075–76.

Exs. 2028, 2045 And 2087 Are Admissible

Exs. 2028, 2045 & 2087 are offered for what they teach, not for the truth of the matters they assert. Thus, they are not hearsay. *See Joy Techs. Inc. v. Manbeck*, 751 F. Supp. 225, 233 n.2 (D.D.C. 1990), *aff'd* 959 F.2d 226 (Fed. Cir. 1992).

Exs. 2028, 2045 & 2087 are relevant because they rebut IBS' allegations of obviousness. Specifically, IBS' petition argued that “in order to improve the efficiency, reliability, and robustness of the sequencing by synthesis method taught” by Ju and Tsien, a PHOSITA would use Zavgorodny's azidomethyl group with a reasonable expectation of success. Paper 7 at 38–39. Exs. 2028, 2045 & 2087 rebut this and establish that a PHOSITA believed this to be a difficult goal to achieve. The exhibits also contradict IBS' unsupported hindsight allegations that the desired efficiencies can be achieved with any group after conventional, trivial, and routine optimization. *Compare* Paper 54 at 6 (citing only to Ex. 1031, ¶¶15–17) *with* Paper 32 at 44–45 (citing Exs. 2011, 2079, 2045, 2024, 2028 & 2077). Ex. 2087 also tends to prove that a PHOSITA would have recognized that high

efficiencies were needed to achieve the desired read lengths. Exs. 2028 & 2045 tend to prove that a PHOSITA would consider finding a suitable 3' protecting group to be a "major challenge" (Ex. 2028, 197–198) and that "inefficient chemistries [] prevent determination of any more than a few nucleotides in a complete sequencing operation." Ex. 2045, 1:51–61. Thus, these exhibits demonstrate that a PHOSITA would not have considered the selection of an azidomethyl as a suitable 3'-OH protecting group to require trivial optimization.

Exs. 2055, 2057, 2059, And 2062 Are Admissible

Exs. 2055, 2057, 2059 & 2062 are relevant to IBS' copying of Solexa/Illumina's novel 3'-OH blocking group, and IBS offers no explanation how these exhibits could be misleading in any way. Exs. 2055, 2057, 2059 & 2062 are theses from Dr. Ju's lab and are at least probative of the fact that Dr. Ju's lab was aware of Solexa/Illumina techniques, which they adopted after Solexa/Illumina commercially launched its product in 2006. *See., e.g.*, Ex. 2055, 99; Ex. 2057, 101, 111, 114, 174 & 190; Ex. 2059, 43 & 51; Ex. 2062, 78; Paper 32 at 57:Figure 2; *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1352 (Fed. Cir. 2012) (evidence of Defendant's awareness of Plaintiff's patents while designing the accused product supported the jury's finding of copying); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1329 (Fed. Cir. 2009) (Defendant's initial attempt at making a rigid pedicle screw

without a claimed feature, together with Defendant's prompt adoption of the claimed feature soon after the patent issued, are relevant indicia of nonobviousness). In addition, IBS admits that it followed the lead of Dr. Ju's lab in switching to the azidomethyl protecting group. Paper 54 at 15.

Moreover, while Illumina bears the burden of production on secondary considerations, IBS bears the ultimate burden of proving obviousness; its attempt to shift the ultimate burden to Illumina is improper. Illumina came forward with credible circumstantial evidence of copying, so it was IBS's burden to provide evidence in rebuttal. The fact that IBS does not deny the allegations of copying and does not provide any countervailing evidence is telling, and further reinforces the merits of Illumina's evidence of copying. *DePuy Spine*, 567 F.3d at 1329.

Exs. 2089, 2058, 2060, And 2091–2121 Are Admissible

IBS seeks to exclude Dr. Burgess' entire expert declaration (Ex. 2089) *and* 32 additional exhibits cited therein. But, this evidence encompasses highly relevant expert analysis of non-excludable exhibits that will assist the Board. IBS presents no meaningful argument for excluding numerous exhibits cited by Dr. Burgess (including, *e.g.*, Exs. 2058, 2060, 2095, 2097–2101 & 2104–13) and thus IBS fails to meet its burden under 37 C.F.R. § 42.20(c). Furthermore, IBS failed to timely object to Exs. 2089, 2058, 2060, 2091, 2097–2101, 2104–2113, & 2120 on hearsay grounds. Ex. 1055, at 10–11, 15, 18–20, 21–26 & 30; 37 C.F.R. § 42.64(c).

IBS Fails to Establish That the Burgess Declaration Violates FRE 702(a)

Any contention that Dr. Burgess is unqualified as an expert must be rejected in view of his extensive publication record and first-hand experience developing nucleotides employing various protecting groups during the relevant time frame and beyond. *See, e.g.*, Ex. 2024 (co-authored with Dr. Metzker); Exs. 2028, 2077 & 2079; Ex. 2089, ¶¶11–12 & 25; Ex. 2154, 114:2–15. Moreover, Dr. Burgess’ publications were cited by those working on SBS around the time of Illumina’s invention. *See, e.g.*, Ex. 1001, 1:56–62 & 5:24–27; Ex. 1002, 2:6–9, 2:26–36, 3:7–9, 26:19–22, 30:62–64, 32:1–4, & 33:11–15; Ex. 2032, 1:19–26; Ex. 2070, 2:18–26. Dr. Burgess’ expertise is substantially greater than that of Dr. Branchaud. *See, e.g.*, Ex. 2082, 159:21–161:19 & 162:17–163:10.

IBS’ contention that Dr. Burgess’ declaration should be excluded under FRE 702(a) because he “interprets the words of the documents and speculates beyond them” (Paper 61 at 8) reflects a misunderstanding of the role of expert witness testimony. The fundamental role of an expert witness is to provide specialized knowledge to help the trier of fact understand the evidence. FRE 702. That is precisely what Dr. Burgess did. IBS’ disagreements with Dr. Burgess’ opinions should have been addressed in cross-examination and/or in its Reply (Paper 54). *See, e.g., INVISTA N. America S.a.r.l. v. M & G USA Corp.*, 2013 WL 3216109, *5 (D. Del. 2013) (Order on Motions to Exclude).

Citing *Rambus Inc. v. Hynix Semiconductor Inc.*, 254 F.R.D. 597, 608 (N.D. Cal. 2008), IBS asserts that Dr. Burgess’s declaration should be excluded because he “does not cite any third-party materials discussing [a long-felt and unmet] need in the industry.” Paper 61 at 9. However, as noted above, Dr. Burgess’ opinions are based on his direct experience during the relevant time frame. *See* Ex. 2089, ¶25; *see also* Exs. 2024, 2028, & 2079. Unlike the expert in *Rambus*, Dr. Burgess’ experience in the relevant time frame is far from “minimal.” *See Rambus*, 254 F.R.D at 608. Moreover, Dr. Burgess’ opinions are supported by numerous third party articles and the opinion of Dr. Romesberg. Paper 32 at 44–47; Ex. 2011, ¶¶59–65. Notably, Dr. Burgess’ opinions were not contradicted by IBS. *See generally* Exs. 1031 & 1046.

IBS’ generic contention that Ex. 2089 circumvents page limits is unsupported. IBS does not allege any specific instance of improper or excessive incorporation. Illumina’s Response (Paper 32) arguments and accompanying citations to Dr. Burgess’ declaration are detailed and specific, as appropriate PTAB practice. *Research in Motion v. Multimedia Ideas*, IPR2013-00036, Paper 15 at 7 (P.T.A.B. Mar. 18, 2013). Further, it is inappropriate to allege improper incorporation by reference in a Motion to Exclude. *Id.* at 8; *Apple v. Sightsound Technologies*, CBM2013-00020, Paper 65 at 3 (P.T.A.B. Apr. 2, 2014).

IBS makes the conclusory assertion that the documents Dr. Burgess relies

upon are deficient due to the selection process. But IBS does not identify how the evidence is substantively deficient nor does IBS identify contradictory evidence. Dr. Burgess was provided with and considered relevant materials. Allegations that Dr. Burgess should have considered more or different information go to the weight of his opinions, not their admissibility. IBS' assertion that Dr. Burgess' opinions are based on insufficient facts or data because he failed to "discuss the issues with any of the declarants" is a red herring: the declarants are employees of IBS and Columbia, who are suing Illumina in parallel litigation. In fact, Dr. Burgess's opinions should be given substantial weight given his experience, the supporting documentation, and IBS' failure to contradict him.

IBS fails to explain why Dr. Burgess cannot reasonably rely on the evidence he considered. Most of the statements that Dr. Burgess relies upon are admissible IBS admissions – not hearsay. FRE 801(d)(2). These include statements by IBS' CEO Steve Gordon (Exs. 2091¹, 2097–8), IBS' VP of R&D Jerzy Olejnik (Exs. 2099–2101 & 2120), and IBS' co-founder Dr. Ju² (Exs. 2117, 2096 & 2102–3). They are thus highly reliable sources for Dr. Burgess to rely upon.

¹ Although Ex. 2091 was produced by Columbia rather than IBS, the language of the document confirms that it was prepared by and for IBS. *See, e.g.*, Ex. 2091 at 4 (discussing [REDACTED]).

² Dr. Ju's role as a co-founder of IBS is undisputed. *See* Ex. 2137, ¶11.

Ultimately, rather than dispute admissibility under FRE 702(b), IBS attacks the substance of Illumina’s evidence. For instance, with regard to Dr. Burgess’ testimony regarding failure of others, IBS complains that Dr. Burgess “gets the documents wrong.” Paper 61 at 10–11. Not so. Dr. Burgess’ evidence shows that

[REDACTED]

[REDACTED]. Ex. 2089, ¶¶43-52. Likewise, it shows that [REDACTED]

Id., ¶¶47-50. Such “[e]vidence of unsuccessful efforts at solving a problem that a claimed invention does . . . solve suggests that a claimed invention is not obvious” and is thus relevant and admissible. *Rambus*, 254 F.R.D. at 608.

IBS Fails to Establish That the Burgess Declaration Is Irrelevant

IBS presents a series of disjointed arguments to exclude Ex. 2089 by alleging that Dr. Burgess failed to establish a nexus between the secondary considerations and the claims. At best, IBS’ arguments go to weight, not admissibility. Dr. Burgess’s opinions regarding long-felt need, copying, and praise are admissible and remain unrebutted, further supporting their accuracy.

IBS improperly argues that Illumina must provide evidence of secondary considerations for the “full scope” of the claim. *See, e.g.*, Paper 61 at 13. But, “[o]bjective evidence of nonobviousness need only be ‘reasonably commensurate with the scope of the claims,’ and we *do not require a patentee to produce*

objective evidence of nonobviousness for every potential embodiment of the claim.” Rambus Inc. v. Rea, 731 F.3d 1248, 1257 (Fed. Cir. 2013) (emphasis added). IBS also mischaracterizes *Geo M. Martin Co. v. Alliance Mach.*, 618 F.3d 1294 (Fed. Cir. 2010). *Geo Martin* is silent as to the value of circumstantial evidence. Here, similar to *Ecolochem Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1376 (Fed. Cir. 2000) (cited to by *Geo Martin*) Illumina’s evidence of copying in combination with evidence of unmet need, unexpected properties, and industry praise supports the nonobviousness of claims. *See also Transocean, supra* at 6.

Regarding “unmet need,” IBS does not dispute that Ju and Tsien are directed to high efficiency SBS, that high-efficiency SBS is within the scope of the claims, and that there was an unmet need for methods of using protected nucleotides for such purposes. At most, IBS’ argument addresses the weight accorded the evidence, rather than admissibility.

Regarding “unexpected properties,” IBS asserts that exceptional results for incorporation of 3’-O-azidomethyl nucleotides “were achieved due to Solexa’s proprietary enzyme” (Paper 61 at 11) and misrepresents Dr. Burgess’ opinions as set forth in Ex. 2089 ¶¶76–78. Such arguments go only to the weight of evidence, not admissibility. Ex. 2089 is relevant and admissible because Dr. Burgess relies on [REDACTED]

[REDACTED]

[REDACTED] (Ex. 2089,

¶72;

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] *Id.*, ¶74. IBS has not identified any basis to exclude this highly relevant evidence.

Regarding industry praise, IBS presents a general list of alleged deficiencies that go to the weight of evidence rather than admissibility. The evidence cited by Dr. Burgess is, however, highly relevant and admissible. Most notably, Dr. Burgess cites praise by [REDACTED]

[REDACTED]. Ex. 2089, ¶83 (citing Ex. [REDACTED]). IBS merely speculates that other reasons might be responsible, and directly contradicts Ex. [REDACTED], which states [REDACTED]

[REDACTED]; *see also* Paper 61 at 13. Praise of others (Exs. 2094, 2116–9, 2121) is not a hearsay use because it is not offered for the truth. FRE 801(c).

Exs. 2139–2152 Are Admissible

IBS moves to exclude Exs. 2139–2152 under 37 C.F.R. § 42.123 as allegedly improper supplemental evidence. Paper 61 at 14–15. A motion to exclude should not attack evidence for being improper supplemental evidence. *Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co.*, CBM2012-00002, Paper 66 at 62:1–4 (P.T.A.B Jan. 23, 2014). IBS’ motion can be denied for at least this reason.

Exs. 2141, 2142, 2148, 2150, 2151 & 2152 are being used to show what the documents convey to a PHOSITA, not for their truth. Therefore, they are admissible. FRE 803(3); *Joy Techs.*, 751 F.Supp. at 233, *supra*.

Also, Dr. Metzker is listed as, and confirmed he was, an author of Exs. 2139, 2143, 2146 & 2147. Ex. 2154, 31:23–32:2, 169:11–170:11, 209:7–210:2, 229:16–231:9. The statements in Dr. Metzker’s patent applications and peer-reviewed publications are also admissible under FRE 807. These documents directly contradict positions that Dr. Metzker has taken in this IPR. For example, in Ex. 2143, ¶75, he stated that hydrophobic solvents denature DNA. This contradicts his opinion in this IPR that Zavgorodny’s hydrophobic pyridine would not denature DNA. Ex. 1046, ¶37.

Conclusion

IBS failed to meet its burden to show that it is entitled to the requested relief, so its Motion to Exclude should be denied in its entirety. 37 C.F.R. § 42.20(c).

Respectfully submitted,

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I hereby certify that a true and correct copy of **ILLUMINA OPPOSITION TO MOTION TO EXCLUDE EVIDENCE** is being served on September 15, 2014, via email pursuant to 37 C.F.R. § 42.6(e) per agreement of the parties, to counsel for Intelligent Bio-Systems, Inc., at the addresses below:

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